REMARKS/ARGUMENTS

In response to the Rejection mailed September 8, 2004, applicants have amended claims 61, 64, 66, 67, 68, 70, 71, 74, 76, 77, 80 and 82 and present the following remarks. Claims 61, 64-71, 74-77 and 80-82 are pending. Claims 1-60, 62, 63, 72, 73, 78 and 79 have been canceled.

Claims 61, 64-71, 74-77 and 80-82 were rejected under 35 USC 112, second paragraph as being indefinite in the term fluorescent antibodies and other terms lacking antecedent basis. These claims have been amended to overcome these objections. As such, the rejection has been overcome.

Claims 61, 64-71, 74-77 and 80-82 were rejected under 35 USC 112, first paragraph, as not meeting the written description requirement. Specifically, the examiner asserts that neither antibody reagents nor methods of practicing the use of such antibodies are disclosed. The examiner notes that many different microorganisms might be present and that many different antibodies would be needed and no disclosure is present as to which antibody to use.

The present invention is generic to the use of many commercially available antibodies for the detection of their corresponding microorganisms. A large number of antibodies, which specifically bind to their microorganism partner, were well known in the prior art and was stated in the Background to the Invention. A number of companies sell antibodies to a large number of microorganisms through their catalogs.

The field of binding antibodies to microorganisms for the purpose of detection is quite old and well established and has been an established part of medical diagnostics for many years. The specificity of antibodies is well known.

It is well within the skill of the art to select an antibody specific to a microorganism for the purpose of binding to and detecting that microorganism without detailed instruction. Likewise, selection of optimal concentrations is also readily determinable without undue experimentation. Accordingly, the disclosure in paragraphs 67-72 alone are more than

sufficient to describe the present invention given the general knowledge of those skilled in the art. Therefore, this rejection should be withdrawn.

Claims 61, 64-71, 74-77 and 80-82 were rejected under 35 USC 112, first paragraph, as not meeting the enabling requirement. The examiner contends that the field of immunoassays is unpredictable and therefore the specification is not enabling. This rejection is traversed.

Contrary to the examiner's position of "The art concerning production and use of antibodies to detect specific microorganisms in specific assays is unpredictable.", hundreds of patents involving immunoassays have been issued. Given a corresponding antibody and antigen, it is fully enabled for one of ordinary skill to make and use an immunoassay.

The examiner has cited Hayrinen et al and Takeda et al to show that some antibodies will decrease in avidity in high ionic strength solutions. The examiner urges that this renders the claimed invention unpredictable. While these papers involve the use of an antibody to a molecular antigen rather than to a microorganism with many epitopes on many different antigens, the principle his similarities and differences.

However, the present invention is banding microorganisms in a density gradient at relatively low ionic strength. As mentioned in paragraph 45 of the specification, viruses are found in a particular "virus window" which is shown in Figure 1. This window is at a density much less than nucleic acids. The ionic strength in the range to give the density and/or sedimentation coefficient where viruses are found does not involve as great an ionic strength. Therefore, one need not be concerned with preventing antibodies from binding to microorganisms.

As shown in Takeda et al, figure 1, different antibodies have different binding avidities at the same ionic strength. Given the large number of different antibodies for various known microorganisms, it is well within the ordinary skill to try and determine which commercially available antibody is best when optimizing the present invention for detecting a particular microorganism. Furthermore, if one uses antisera, one has a mixture of many antibody molecules binding to many different microbial antigens. Even if some

become unbound in the higher ionic strength solution, others will still bind. Accordingly, the rejection should be withdrawn.

In view of the above amendments and comments, the claims are now in condition for allowance and applicants request a timely Notice of Allowance be issued in this application. If needed, applicants petition for sufficient extension of time for consideration of this paper.

The commissioner hereby is authorized to charge payment of any fees, including extension of time fees, under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No.500933.

Respectfully submitted,

Date: December 8, 2004

John E. Tarcza
Reg. No. 33,638

John E. Tarcza
Intellectual Property Advisor
Large Scale Biology Corporation
3333 Vaca Valley Parkway, Suite 1000
Vacaville, CA 95688
301-371-7740 tel.
301-371-7745 Fax.
E-MAIL john.tarcza@lsbc.com